

106TH CONGRESS  
1ST SESSION

# S. 117

To permit individuals to continue health plan coverage of services while participating in approved clinical studies.

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IN THE SENATE OF THE UNITED STATES

JANUARY 19, 1999

Ms. SNOWE introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To permit individuals to continue health plan coverage of services while participating in approved clinical studies.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Improved Patient Ac-  
5 cess to Clinical Studies Act of 1999”.

6 **SEC. 2. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**  
7 **APPROVED CLINICAL STUDIES.**

8 (a) AMENDMENTS TO ERISA.—

9 (1) IN GENERAL.—Subpart B of part 7 of sub-  
10 title B of title I of the Employee Retirement Income

1 Security Act of 1974 (29 U.S.C. 1185 et seq.) (as  
2 amended by the Women’s Health and Cancer Rights  
3 Act of 1998) is further amended by adding at the  
4 end the following new section:

5 **“SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**  
6 **APPROVED CLINICAL STUDIES.**

7 “(a) PERMITTING PARTICIPATION IN APPROVED  
8 CLINICAL STUDIES.—A group health plan, and a health  
9 insurance issuer offering health insurance coverage in con-  
10 nection with a group health plan, may not deny (or limit  
11 or impose additional conditions on) the coverage of items  
12 and services furnished to an enrollee if—

13 “(1) the enrollee is participating in an approved  
14 clinical study;

15 “(2) the items and services are furnished ac-  
16 cording to the design of the study or to treat condi-  
17 tions resulting from participation in the study; and

18 “(3) the items and services would otherwise be  
19 covered under the plan except for the fact that the  
20 items and services are provided in connection with  
21 participation in such a study.

22 Such a plan or issuer may not discriminate against an  
23 enrollee on the basis of the enrollee’s participation in such  
24 a study.

1       “(b) CONSTRUCTION.—Nothing in subsection (a)  
 2 shall be construed as requiring a group health plan, or  
 3 a health insurance issuer offering health insurance cov-  
 4 erage in connection with a group health plan, to provide  
 5 for payment for items and services normally paid for as  
 6 part of an approved clinical study.

7       “(c) APPROVED CLINICAL STUDY DEFINED.—In this  
 8 section, the term ‘approved clinical study’ means—

9               “(1) a research study approved by the Sec-  
 10 retary of Health and Human Services, the Director  
 11 of the National Institutes of Health, the Commis-  
 12 sioner of Food and Drugs, the Secretary of Veterans  
 13 Affairs, the Secretary of Defense, or a qualified non-  
 14 governmental research entity (as defined in guide-  
 15 lines of the National Institutes of Health); or

16               “(2) a peer-reviewed and approved research  
 17 program, as defined by the Secretary of Health and  
 18 Human Services, conducted for the primary purpose  
 19 of determining whether or not a treatment is safe,  
 20 is efficacious, or has any other characteristic of a  
 21 treatment that must be demonstrated in order for  
 22 the treatment to be medically necessary or appro-  
 23 priate.”.

24       “(2) TABLE OF CONTENTS.—The table of con-  
 25 tents in section 1 of the Employee Retirement In-

1        come Security Act of 1974 (29 U.S.C. prec. 1001)  
 2        is amended by inserting after the item relating to  
 3        section 713 the following:

“Sec. 714. Coverage for individuals participating in approved clinical studies.”.

4        (b) AMENDMENTS TO PHSA.—

5            (1) GROUP MARKET.—Subpart 2 of part A of  
 6        title XXVII of the Public Health Service Act (29  
 7        U.S.C. 300gg–4 et seq.) (as amended by the Wom-  
 8        en’s Health and Cancer Rights Act of 1998) is fur-  
 9        ther amended by adding at the end the following  
 10       new section:

11    **“SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING**  
 12                            **IN APPROVED CLINICAL STUDIES.**

13        “(a) PERMITTING PARTICIPATION IN APPROVED  
 14    CLINICAL STUDIES.—A group health plan, and a health  
 15    insurance issuer offering health insurance coverage in con-  
 16    nection with a group health plan, may not deny (or limit  
 17    or impose additional conditions on) the coverage of items  
 18    and services furnished to an enrollee if—

19            “(1) the enrollee is participating in an approved  
 20        clinical study;

21            “(2) the items and services are furnished ac-  
 22        cording to the design of the study or to treat condi-  
 23        tions resulting from participation in the study; and

24            “(3) the items and services would otherwise be  
 25        covered under the plan except for the fact that the

1 items and services are provided in connection with  
2 participation in such a study.

3 Such a plan or issuer may not discriminate against an  
4 enrollee on the basis of the enrollee's participation in such  
5 a study.

6 “(b) CONSTRUCTION.—Nothing in subsection (a)  
7 shall be construed as requiring a group health plan, or  
8 a health insurance issuer offering health insurance cov-  
9 erage in connection with a group health plan, to provide  
10 for payment for items and services normally paid for as  
11 part of an approved clinical study.

12 “(c) APPROVED CLINICAL STUDY DEFINED.—In this  
13 section, the term ‘approved clinical study’ means—

14 “(1) a research study approved by the Sec-  
15 retary of Health and Human Services, the Director  
16 of the National Institutes of Health, the Commis-  
17 sioner of Food and Drugs, the Secretary of Veterans  
18 Affairs, the Secretary of Defense, or a qualified non-  
19 governmental research entity (as defined in guide-  
20 lines of the National Institutes of Health); or

21 “(2) a peer-reviewed and approved research  
22 program, as defined by the Secretary of Health and  
23 Human Services, conducted for the primary purpose  
24 of determining whether or not a treatment is safe,  
25 is efficacious, or has any other characteristic of a

1 treatment that must be demonstrated in order for  
 2 the treatment to be medically necessary or appro-  
 3 priate.”.

4 (2) INDIVIDUAL MARKET.—Subpart 3 of part B  
 5 of title XXVII of the Public Health Service Act (29  
 6 U.S.C. 300gg–51 et seq.) (as added by section  
 7 605(a) of the Newborn’s and Mother’s Health Pro-  
 8 tection Act of 1996 and amended by the Women’s  
 9 Health and Cancer Rights Act of 1998) is further  
 10 amended by adding at the end the following new sec-  
 11 tion:

12 **“SEC. 2753. COVERAGE FOR INDIVIDUALS PARTICIPATING**  
 13 **IN APPROVED CLINICAL STUDIES.**

14 “The provisions of section 2707 shall apply to health  
 15 insurance coverage offered by a health insurance issuer  
 16 in the individual market in the same manner as the provi-  
 17 sions apply to health insurance coverage offered by a  
 18 health insurance issuer in connection with a group health  
 19 plan in the small or large group market.”.

20 **SEC. 3. EFFECTIVE DATE.**

21 The amendments made by this Act shall apply—

22 (1) with respect to group health plans for plan  
 23 years beginning on or after January 1, 2000; and

24 (2) with respect to health insurance coverage  
 25 offered, sold, issued, renewed, in effect, or operated

- 1 in the individual market on or after January 1,
- 2 2000.

